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2200 SAND HILL ROAD STE 100			
MENLO PARK, CA 94025			

1814

EXAMINER

01/10/96

ART UNIT

PAPER NUMBER

37

DATE MAILED:

This is a communication from the examiner in charge of your application.
 COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 10/20 & 11/28, 1995 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 4-7, 9-15, 19 & 23-33 are pending in the application.
 Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 4-7, 9-15, 19 & 23-33 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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EXAMINER'S ACTION

5 Claims 4-7, 9-16, 19, 23-29 and new claims 30-33 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to methods of producing an alkalophilic asporogenic Bacillus novo species PB92 of minimal natural extracellular protease level, transformed with a B. novo PB92 alkaline protease which has been mutated as described in the specification. Claims 30-33 are included for the same reasons as the previously rejected claims. See M.P.E.P. §§ 706.03(n) and 706.03(z).

10 Applicants' arguments concerning the mutation of the high alkaline protease gene have been deemed persuasive. Applicants have convincingly demonstrated that the mutation to the protease per se is not the significant part of the application and invention, as stated, for example, at the sentence bridging pages 12-13.

15 The claims are not properly enabled for the recitation of any "mutant high alkaline protease", and any "alkalophilic Bacillus strain". Applicants have stated that the strain PB92 has been used merely as an example, and that the specification provides enablement for the use of other types of these strains, and for other "mutant high alkaline proteases". Applicants further state that techniques for such are
20 "routine and require no inventive skill or undue experimentation" (pg. 7, response of 9-7-93). This is not deemed persuasive for the reasons of record. Primarily, the specification has not provided pertinent information regarding any other "high alkaline protease" gene, nor any appropriate Bacillus strain that would satisfy the requirements of the
25 invention. This fact is important, as the claims are not commensurate in scope with the specification and its enablement. This information is essential to the function of the claimed invention, and the essential material may not be improperly incorporated into the specification, and does not find support within the teachings of the specification. There

5 is no teaching or reasonable expectation provided that one skilled in the art would be able to utilize the teachings provided for any other systems/genes, or even that there is a problem with any other source such that the instant invention would be applicable. Absent this knowledge, one skilled in the art is left with an undue amount of experimentation, due to the breadth of the claims, in order to attempt to determine what other Bacilli or proteases would be useful in the instant invention, and then further attempt to find the gene and apply the principles taught herein. Thus, one skilled in the art would in no way be enabled to practice the claimed invention with any such gene or strain other than the enabled Bacillus PB92.

10 The specification is not properly enabled for claims to any "derivative thereof" of a Bacillus novo species PB92. Applicants state that passages on page 12 of the specification refer to known "derivatives", and that this would be enabling for the instant invention. 15 The phrase "derivatives thereof", however, encompasses predetermined and random mutants of the strain, and progeny of the strain that may or may not contain the gene for the "mutant high alkaline protease" and/or a revertant strain with the indigenous gene. The specification does not properly teach nor describe to one skilled in the art these "derivatives", what specifically they entail, nor how to obtain and/or use such. 20 Mere reference to other teachings, when this is a matter of essential material, without an instant and specific teaching as to how these would be applicable, is not sufficient. Thus, this results in undue experimentation for one skilled in the art to attempt to produce such without proper guidance from the specification. 25

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5 New claim 29 is not properly enabled by the teachings of the
specification for the host strain to be "substantially incapable of
reversion". The specification, at page 7, lines 16-17, teach that the
invention is (preferably) a "non-reverting mutation". This clearly
10 conflicts with the phrase "substantially incapable". Thus, one skilled
in the art has not been taught by the specification, nor is enabled for,
the production of such strains that are only "substantially incapable"
of reversion. Similarly, since this is the case, and the gene encoding
the high alkaline protease has been deleted, then it follows that there
15 should be no "indigenous" alkaline protease product. Thus, it also
follows that such a strain could not be "substantially free" of an
indigenous alkaline protease, but instead, only completely free. The
teachings of the specification do not provide support for such a strain
being "substantially free", nor does the specification teach one skilled
in the art how to produce such a strain.

20 It should be noted that applicants have pointed out, at page 17 of
the response filed 11-22-94, that the Examiner has erred in rejecting
claim number 9 under 35 USC 112, 1st paragraph. This is not deemed
persuasive. Although the claim is specific with regard to the source of
the protease gene, it has not overcome all the deficiencies specified
above for the claim(s) from which it is dependent (ultimately claim 23).
This can be easily seen, for example, if the limitations of claim 9 were
to be included with the limitations of the claims it depends upon in one
singular claim. Thus, it is specific (clearly enabled) for one aspect,
25 but not all, and is still properly rejected.

Claim 23, and thus dependent claims 4-11, and claim 30, and thus
dependent claims 31-33 are rejected under 35 U.S.C. § 112, second

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paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 Claims 23 and 30 are indefinite, as the recitation of the phrase "substantially free of indigenous" protease at line 2, while line 5 conflicts with the phrase "no detectable indigenous" protease. The relationship of "substantially free" and "no detectable" would not appear to be the same, and thus they directly conflict with one another within the claims.

10 The following is a quotation of the first paragraph of 35 U.S.C. § 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 The amendment filed 11-22-94 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the
25 original disclosure is as follows: The phrases "minimal indigenous extracellular protease level", and "a specifically-mutated Bacillus novo PB92 alkaline protease" (underlining added for emphasis) in claim 28.

30 Applicants, at page 8 of the response, have stated that since the Examiner "indicated as enabled" these phrases, that a claim quoting these phrases seemed proper. This is not. These phrases are merely quotes from the Office Action, in the Examiner's shorthand manner of expressing the enablement of the specification. Obviously, the specification deals

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5 with very low levels of expression product, but does not exactly mention "minimal indigenous" protease. Although the two might be grammatically interchangeable, this was not a suggestion or invitation to use this in the claims. This also applies to the phrase "specifically-mutated", which was a shorthand way of avoiding the listing of each mutation used or available to applicant.

Applicant is required to cancel the new matter in the response to this Office action.

10 The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed. This is deemed necessary for the reasons recited immediately above.

15 Claim 28 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth immediately above in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

20 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25
30 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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5 Claims 4-7, 9-16, 19, and 23-29 and new claims 30-33 are rejected under 35 U.S.C. § 103 as being unpatentable over Fahnestock et al. and Estell et al., in view of TeNijenhuis and Suggs et al. The references and rejection are herein incorporated as cited in a previous Office Action.

10 Applicants' arguments filed in response to this rejection have been fully considered but they are not deemed to be persuasive. Arguments submitted 11-22-94 do not substantially differ from those already presented previously, and thus are not deemed persuasive for the reasons of record. Regarding claims 30-33, they are included for the same reasons as the previously rejected claims. Also, it is noted that claims 30-33 read upon a method of isolating the enzyme from a culture broth, which was well known in the art at the time the invention was made. The limitations of the host cell from which the enzyme is isolated does not
15 render the steps of the method (only recited as isolating, and nothing else) patentable, *per se*.

20 NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959.

25 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


KEITH D. HENDRICKS
PATENT EXAMINER
GROUP 1800